

UC Irvine

UC Irvine Previously Published Works

Title

Safety of Beta-hCG plus Erythropoietin in Acute Ischemic Stroke.

Permalink

<https://escholarship.org/uc/item/8667175f>

Journal

STROKE, 40(4)

ISSN

0039-2499

Authors

Cramer, Steven C
Fitzpatrick, Camille
Warren, Michael
et al.

Publication Date

2009

Copyright Information

This work is made available under the terms of a Creative Commons Attribution License, available at <https://creativecommons.org/licenses/by/4.0/>

Peer reviewed

Safety of Beta-hCG+Erythropoietin in Acute Ischemic Stroke.

Steven C Cramer, Camille Fitzpatrick, Michael Warren, Lawrence Plon, Univ of California, Irvine, Irvine, CA; Laura Whitaker, Hoag Memorial Hosp Presbyterian, Newport Beach, CA; Karla Jo Ryckborst, Univ of Calgary, Calgary, Canada; David Brown, Hoag Memorial Hosp Presbyterian, Newport Beach, CA; Michael Hill; Univ of Calgary, Calgary, Canada

Objectives: There are no approved medications to treat stroke beyond the third hour. Studies in animals and in humans suggest that erythropoietin might improve outcome when administered within a multi-hour time window after stroke onset. Also, addition of a second neurotrophic factor might augment erythropoietin effects. The current investigation is a three center, single dose, open label, non-controlled, Phase IIa study to assess the safety of beta-hCG followed by erythropoietin (B-E therapy) in the treatment of early stroke. **Methods:** Entry criteria included supratentorial ischemic stroke <48 hours in duration, age 21–85 years, and NIHSS 6–24. Treatment consisted of a 9-day B-E therapy course, consisting of 3 once-daily IM hCG doses on days 1, 3 and 5 followed by a one day washout period (day 6), followed by 3 daily IV erythropoietin doses on days 7, 8, and 9. **Results:** Of the 15 eligible patients enrolled, 2 died, neither related to study therapy: one with multiorgan failure plus abdominal hemorrhage from heparin for concomitant MI; and one on day 26 of cardiac arrest in setting of subarachnoid hemorrhage. The latter patient also had an arm DVT on day 5, and thus received no erythropoietin. One of 13 patients receiving the day 42 leg duplex showed a DVT (in the calf). One patient with atrial fibrillation had two additional cerebral emboli prior to erythropoietin, received the full B-E therapy course, and did well (day 90 NIHSS=3). Of patients assessed through day 90, NIHSS score improved from baseline 9 ± 4 to 3 ± 2 (mean \pm SD), Barthel at day 90 was ≤ 95 in 8/12, and significant domain-specific gains were measured in motor, language, and attention. Serum hemoglobin did not increase significantly across any of the five assessments over 42 days, though reticulocyte count did. The day 90 infarct volume (n=7) was $22 \pm 34\%$ lower than at baseline. **Conclusions:** A 9 day course of beta-hCG+Erythropoietin started within 48 hours of stroke onset is safe, had minimal hematological effects, and was associated with significant clinical gains. A randomized, placebo-controlled trial of B-E therapy in patients with stroke is therefore appropriate, and has been initiated. CLINICALTRIALS.GOV IDENTIFIER: NCT00362414.